

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

GENETIC TECHNOLOGIES LIMITED,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 12-1736-LPS
v.	)	
	)	
LABORATORY CORPORATION OF AMERICA	)	
HOLDINGS, LABORATORY CORPORATION	)	
OF AMERICA, and 23ANDME, INC.,	)	
	)	
Defendants.	)	

**LABORATORY CORPORATION OF AMERICA HOLDINGS, LABORATORY  
CORPORATION OF AMERICA, AND 23ANDME, INC.'S MOTION TO DISMISS**

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1095933 / 39810

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## **I. INTRODUCTION**

It is well established that laws of nature, natural phenomena, and discovered facts about the world are not eligible for patent protection. But Genetic Technologies Limited (GTG) asserts infringement of just such a patent. GTG claims to have discovered a fact about the human body: that people with a particular genetic variation are better sprinters than those without it. GTG's patent does not claim a modification that improves sprinting, or a drug that makes you run faster. Nor does it claim any change to the individual diagnosed as a likely or unlikely sprinter. It claims the discovery of a fact about the world, pure and simple. The Supreme Court recently made clear that such discoveries are not entitled to patent protection as a matter of law. GTG's complaint should accordingly be dismissed without leave to amend.

## **II. STATEMENT OF FACTS**

GTG asserts infringement of U.S. Patent No. 7,615,342 B2 (the '342 patent), claim 1 of which is directed to

1. A method to predict potential sprinting, strength, or power performance in a human comprising:
  - a) analyzing a sample obtained from the human for the presence of one or more genetic variations in alpha-actinin-3 (ACTN3) gene;
  - b) detecting the presence of two 577R alleles at the loci encoding amino acid number 577 of the alpha-actinin-3 (ACTN3) protein; and
  - c) predicting the potential sprinting, strength, or power performance of the human, wherein the presence of two copies of the 577R allele is positively associated with potential sprinting, strength, or power performance.

While the complaint says that claim 1 is asserted only as an "exemplary" claim, the complaint is entirely devoid of allegations that Defendants infringe any other claim of the patent. Dependent claims of the '342 patent identify and characterize the particular variation in the gene of interest

(claims 2, 11, and 12), predict sprinting ability in males or females (claims 13 and 14), or identify particular locations of the sample in the human body or how they are to be assayed (claims 2-8). Notably, the complaint does not allege that Defendants draw samples from human skeletal muscle (claims 3 and 5) or that it uses a measurement technique described in any of those claims.

Other claims of the '342 patent are directed to using the knowledge derived from the genetic variation to pick a particular sport at which the individual is likely to excel (claim 10) or designing a training regimen for a sprinter based on this knowledge (claim 9). But GTG's complaint asserts only claim 1, and offers no evidence to suggest that Defendants are involved in picking sports for individuals or designing training regimens.

According to the complaint, 23andMe sells testing kits to customers, but the kits are mailed to LabCorp for analysis and "LabCorp thus performs the desired ACTN3 testing for the purchaser." Complaint, D.I. 1 ¶ 18.

### **III. ARGUMENT**

#### **A. Legal Standard**

Patentable subject matter is a pure question of law measured by the four corners of the patent and not dependent on any subsidiary factual determinations, making it appropriate for resolution in a pretrial motion. *See In re Bilski*, 545 F.3d 943, 951 (Fed. Cir. 2008) (*en banc*), *aff'd sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010); *In re Comiskey*, 554 F.3d 967, 975 (Fed. Cir. 2009); *Cybersource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1369, 1376-77 (Fed. Cir. 2011) (affirming grant of summary judgment); *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1334 (Fed. Cir. 2012) (same); *Cyberfone Systems, LLC v. CellCo P'ship*, C.A. No. 11-827-SLR, – F. Supp. 2d –, 2012 WL 3528115 (D. Del. Aug. 16, 2012) (granting an early motion for summary judgment based on section 101); *Cardpool, Inc. v. Plastic Jungle, Inc.*, No. C 12-04182 WHA,

2013 WL 245026 at \*3-4 (N.D. Cal. Jan. 22, 2013) (resolving patentable subject matter issue on a motion to dismiss). Indeed, patentable subject matter is a “threshold test” that determines whether the patent claims are eligible for patent protection. *See Bilski*, 130 S. Ct. at 3225.

Accordingly, resolving this issue before any inquiry into whether the claimed invention is novel, nonobvious, or sufficiently described makes sense. *See SmartGene, Inc. v. Advanced Biological Labs., SA*, 852 F. Supp. 2d 42, 51-52 (D.D.C. 2012) (noting that *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289 (2012), advises section 101 issues to be resolved first).<sup>1</sup>

**B. The '342 Patent Improperly Claims Only the Discovery of Information About the World**

“Laws of nature, natural phenomena, and abstract ideas are not patentable.” *Mayo*, 132 S. Ct. at 1293 (citations omitted). Patent law protects those who make something new or develop a process that transforms the world in some way. It is not a reward for the simple discovery of information. Einstein’s discovery that  $E = mc^2$  was unquestionably significant, but it was not patentable. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (“Einstein could not patent his celebrated law that  $E = mc^2$ ; nor could Newton have patented the law of gravity.”).

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<sup>1</sup> Several weeks before the Supreme Court’s decision in *Mayo* issued, a divided panel of the Federal Circuit had held that where a section 102 issue was fully presented and appropriate for decision as a question of law, deciding the section 102 issue first might be preferable in order to avoid ruling on a patentable subject matter issue not presented below. *See MySpace, Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1261-62 (Fed. Cir. 2012). The Federal Circuit made clear, however, that it was not compelling the practice, stating that district courts had broad discretion and authority to address the order of litigation issues. *Id.* at 1261. Judge Mayer dissented, reasoning that section 101 is a threshold issue that must be decided before other validity issues can be reached, even where it was not resolved in the district court. *Id.* at 1264 (Mayer, J., dissenting). In *Mayo*, the Supreme Court expressed the concern that focusing on section 102 first would render section 101 “a dead letter.” *Mayo*, 132 S. Ct. at 1303. The district court in *SmartGene* therefore concluded that *Mayo* overruled *MySpace* and that *Mayo* requires that patentable subject matter be addressed first. *See SmartGene*, 852 F. Supp. 2d at 51-52. In any event, the Federal Circuit did *not* hold in *MySpace* that other issues pertaining to invalidity must be decided first, but only that section 101 was not a jurisdictional matter that had to be resolved first regardless of the issues briefed.

In *Mayo*, the Supreme Court applied that principle to invalidate a patent claim for a method of assessing the proper dosage of a thiopurine drug. That method included steps of administering a drug to a patient, testing the patient to determine the level of metabolization of the drug, where – according to the patentee’s discovery – a metabolization rate below a certain level indicated a need to increase the drug dosage, and a metabolization rate above a different level indicated a need to reduce the drug dosage. The Supreme Court held that the claimed invention was no more than the discovery of a fact about the world – that different patients metabolized the drug at different rates, and that a certain metabolization range was optimal. The Court rejected the patentee’s argument that it physically transformed the patients by dosing them with a drug, noting that the dosage step was already well-known in the art. “[S]imply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.” *Mayo*, 132 S. Ct. at 1300. The implementation itself, not just the concept, must be specific and inventive. *Id.* at 1293-94.

The ’342 patent has even less connection to a transformation or change in the physical world than did the claim rejected in *Mayo*. Claim 1 does not even require interaction with the patient at all. It requires “analyzing a sample obtained from” a person, but neither the step of obtaining the sample, the nature of the sample, or how the sample is analyzed are specified at all in the claim. In any event, taking a sample of something and analyzing it, without more, are “conventional steps, specified at a high level of generality.” The patent claim does involve detecting the presence of two alleles in the sample and using their presence to predict the sprinting potential of the person. But that merely involves a discovery of a fact about the world

– that “the presence of two copies of the 577R allele” is “positively associated with potential sprinting, strength, or power performance.” ’342 patent, claim 1.

Nor does the ’342 patent make any use of that knowledge to change the world. The claim in *Mayo* at least indicated that the presence of a low level of the drug metabolite was “indicative of a need” to raise the drug dosage. That was insufficient for patentability:

[T]he claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

*Mayo*, 132 S. Ct. at 1298. Here, claim 1 does not even involve routine additional steps. It does not suggest *any* use of the information the patentee has discovered about the world. It merely requires “predicting” potential sprinting performance, something that can be done in the human mind and that does not transform or change the outside world in any tangible way. *Ass’n for Molecular Pathology v. United States*, 689 F.3d 1303, 1335 (Fed. Cir. 2012) (claim unpatentable where “the comparison between the two sequences can be accomplished by mere inspection alone.”), *cert. granted on other grounds sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 694 (2012).

Federal Circuit cases since *Mayo* confirm that claims like this one that merely use a discovery of a fact about the world to predict a human medical condition are not patentable subject matter. In *Ass’n for Molecular Pathology*, the court rejected claims that similarly required comparing a patient’s DNA sequence to a reference sample to determine whether the patient had a particular mutation. The Federal Circuit held those claims invalid because they “recite[] nothing more than the abstract mental steps necessary to compare two different

nucleotide sequences. . . .” *Id.* at 1334. The claims were not directed to an *application* of the mental process of comparing. “Rather, the step of comparing two DNA sequences [was] the entire process that [was] claimed.” *Id.* at 1335.

Nor can GTG avoid this result by reading in implicit steps of collecting physical samples from a patient or sequencing the allelic variations it has identified. *Ass’n for Molecular Pathology* rejected just such an effort:

To avoid this result, Myriad attempts to read into its method claims additional, allegedly transformative steps. As described above, Myriad reads into its claims the steps of (1) extracting DNA from a human sample, and (2) sequencing the *BRCA* DNA molecule, arguing that both steps necessarily precede the step of comparing nucleotide sequences. The claims themselves, however, do not include either of these steps. The claims do not specify any action prior to the step of “comparing” or “analyzing” two sequences; the claims recite just the one step of “comparing” or “analyzing.”

*Id.* See also *In re Grams*, 888 F.2d 835, 840 (Fed. Cir. 1989) (“The presence of a physical step in the claim to derive data for the algorithm will not render the claim statutory.”).

In the wake of *Mayo* and *Association for Molecular Pathology*, it is clear that a patent claim that merely uses a discovery about a genetic relationship to diagnose a particular disease or other condition is not patentable subject matter. Indeed, the rule is so settled that the Federal Circuit did not even deem it worth publishing its most recent rejection of a claim like GTG’s.<sup>2</sup> In *PerkinElmer, Inc. v. Intema Ltd.*, No. 2011-1577, 2012 WL 5861658, at \*5-6 (Fed. Cir. Nov. 20, 2012), the court rejected claims phrased in language remarkably similar to GTGs. Those claims involved determining whether a pregnant woman was at increased risk of fetal Down’s syndrome by assaying a sample from the mother, measuring the level of particular markers the

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<sup>2</sup> Fed. Cir. R. 32.1 permits the citation of non-precedential opinions for “guidance or persuasive reasoning.” *Id.* R. 32.1(d). The fact that the opinion is unpublished suggests that the opinion is “one determined by the panel issuing it as not adding significantly to the body of law.” *Id.* R. 32.1(b).

patentee had identified, and determining the risk of Down's syndrome by comparing the two. Indeed, Intema's patent involved more testing detail than does claim 1 here; the patients were separated into different groups based on an initial screen, and the relationship it tested was a complex one that involved measuring frequency distributions. Nonetheless, the Federal Circuit had no trouble rejecting that claim as patent-ineligible:

Since Intema's claims recite mental processes and natural laws, we must decide if Intema added enough to the statements of ineligible subject matter to direct the claims, not to the ineligible concepts themselves, but to applications of those concepts. We think not.

The 'measuring' steps are insufficient to make the claims patent-eligible. They merely tell the users of the process to measure the screening markers through whatever known method they wish. . . .

Nor is the 'determining' step sufficient. This step requires the ineligible mental step of 'comparing' the measured markers 'with observed frequency distributions . . . to determine the risk of fetal Down's syndrome.

. . . [A]nyone who wants to use this mental step or natural law must follow the claimed process. And, as in *Mayo*, there is no requirement that a doctor act on the calculated risk. There is at most 'a suggestion' that the doctor take the mental determination into account when assessing the patient. The claims are thus ineligible under section 101.

*Id. Accord Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1067-68 (Fed. Cir. 2011) (pre-*Mayo* decision invalidating claims that "do not include putting [] knowledge to practical use, but are directed to the abstract principle that variation . . . may have consequences for certain diseases."), *cert. denied sub nom. GlaxoSmithKline v. Classen Immunotherapies, Inc.*, 133 S. Ct. 973 (2013). GTG's patent uses different words – "analyzing" instead of "measuring," "detecting" instead of "determining," "predicting" instead of "suggesting" – but the structure of claim 1 otherwise parallels the claim rejected in *PerkinElmer*.<sup>3</sup>

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<sup>3</sup> The unasserted dependent claims that could conceivably be asserted against defendants fare no

GTG claims no more than a discovery of a fact about the world – the relationship between two 577R alleles and sprinting – and the mental step of “predicting” sprinting on the basis of finding those alleles. The law is clear that such claims are unpatentable as a matter of law. This result doesn’t depend on facts or things GTG might replead. It is the patent itself that is fatally deficient, and no amount of artful pleading can change that result. So amendment would be futile. *See Cardpool*, 2013 WL 245026, at \*4 (granting motion to dismiss on patentable subject matter without leave to amend).

#### IV. CONCLUSION

This Court should dismiss GTG’s complaint without leave to amend.

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better. Claim 12, for example reads “[t]he method of claim 1, wherein the 577R allele is a SNP.” A SNP is a “single nucleotide polymorphism,” meaning that it differs from the normal gene only by changing a single codon. The discovery of the relationship between the presence of the 577R allele and sprinting is an unprotectable fact about the world regardless whether the naturally-occurring allele is a SNP or not.

Claim 6 adds particular possible methods of detecting the allele in the human sample: “DNA sequencing, allele-specific hybridization, allele-specific amplification or restriction fragment length polymorphism analysis.” But GTG does not claim to have invented any of these methods; each is well-known in the art. They are the “conventional steps” the Supreme Court declared insufficient for patentability. *Mayo*, 132 S. Ct. at 1300 (“simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.”).

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

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